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10/538,130	06/29/2006	Ghislaine Tissot	09879-00064-US	1355
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CONNOLLY BOVE LODGE & HUTZ, LLP			EXAMINER	
P O BOX 2207			KUBELIK, ANNE R	
WILMINGTON, DE 19899			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,130	Applicant(s) TISSOT ET AL.
	Examiner Anne R. Kubelik	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on **21 July 2008**.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) **1-16** is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) **1-16** is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. Claims 1-16 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claims 5, 11 and 14 because informalities is withdrawn in light of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 102

4. Claims 1-3, 6-8 and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniell (US Patent 7,129,391, filed 15 May 1998). The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 February 2008X. Applicant's arguments filed 21 July 2008 have been fully considered but they are not persuasive.

Daniell claims soybean, peanut and pea plants whose chloroplasts are stably transformed (claims 75-77 and 81-83) and a method of producing them (claim 92). Daniell indicates that stably transformed plants have progeny with the transformation event (column 7, line 10-13); thus, the plants must be fertile. The process inserts the expression cassette into an intergenic region (claim 84) and was done by particle bombardment (column 27, lines 39-67).

Daniell also claims plastid transformation vectors comprising an expression cassette encoding a selection marker two sequences homologous with a portion of a legume plastome, wherein the sequences flank an expression cassette encoding a peptide of interest (claims 3 and 95); the flanking sequences are homologous because they are competent to undergo homologous recombination with the plastid sequence of the target plant, and because they are used to produce

the plastid-transformed soybean, peanut and pea plants of claims 75-77 and 81-83). The expression cassettes comprise 5' and 3' expression control sequences (claims 3 and 84), which include a Prnr promoter and a psbA terminator (Fig 2).

Applicant urges that '391 does not contain an enabling disclosure of fertile transplastomic leguminous plants; example 5 and 6 of that patent only described general steps of peanut and soybean plastid transformation, Fig 14 and 15 show that peanut and soybean embryonic shoots are resistant to the antibiotic used for selection, and there is no disclosure of fertile peanut or soybean plants (response pg 10-11).

This is not found persuasive because the issued claims are drawn to soybean, peanut and pea plants whose chloroplasts are stably transformed. The instant specification has shown that transformation of soybean plastids using the aadA selection marker is possible.

Applicant urges that Zhang reported an attempt to transform plastids of soybean suspension cell cultures, and that soybean was not among the list of previously transformed plastids (response pg 11).

This is not found persuasive because Zhang does not provide evidence that it was not thought possible to transform soybean; if fact, Zhang said that it should be possible (Abstract).

Applicant urges that Daniell 2005 indicates that the first successful attempt to transform soybean plastids was made by Dufourmantel et al, thus implicitly acknowledging that '391 was not a disclosure of fertile transplastomic soybeans (response pg 11).

This is not found persuasive because Daniell 2005 did not say he attempted soybean transformation and was unsuccessful.

Applicant urges that Dufourmantel et al lists only tobacco, tomato and *Lesquerella* as other fertile transplastomic plants (response pg 12).

This is not found persuasive because claims are issued patents are presumed enabled until proven otherwise. Dufourmantel et al does nothing to prove that making fertile transplastomic soybeans is not possible; in fact, it demonstrates that '391 is enabled.

Applicant urges that '391 does not anticipate the vectors of claims 7-8 and 13 because it contains tobacco chloroplast flanking sequences (response pg 12).

This is not found persuasive because tobacco chloroplast flanking sequences would be "comprise ... sequences homologous with a zone of the plastome of [a] leguminous plant". The size of the homolog is not recited in the claim; the vector of '391 certainly has at least two nucleotides in common with legume plastid genome.

Applicant urges that the methods of claims 14-15 are not anticipated as '391 did not result in fertile transplastomic leguminous plants (response pg 12).

This is not found persuasive because claims are issued patents are presumed enabled until proven otherwise. Applicant has not so proven '391 not enabled.

Claim Rejections - 35 USC § 103

5. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maliga et al (1999, US Patent 5,877,402) in view of von Allmen (1992, GenBank Accession No. X07675). The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 February 2008. Applicant's arguments filed 21 July 2008 have been fully considered but they are not persuasive.

The claims are drawn to fertile transplastomic legumes, including soybeans, wherein the plants have been transformed with a plastid transformation vector comprising expression cassettes flanked by soybean plastid sequences from a region encoding the rRNA, trnV and rps12.

Maliga et al teach a method of tobacco plastid transformation by particle bombardment using a vector comprising expression cassettes comprising the aadA selection marker and a gene of interest, each operably linked to a plastid promoter and plastid terminators, wherein the expression cassettes are flanked by tobacco plastid sequences from a region encoding the 16S rRNA, trnV and rps12/7 (column 22, lines 13-30, column 22, line 59, to column 25, line 67; column 27, lines 14-59; column 51, line 59, to column 57, line 40; Fig 17C, 18, 19, 22).

McBride et al do not disclose a method of soybean plastid transformation a vector comprising expression cassettes comprising the aadA selection marker and a gene of interest, each operably linked to a plastid promoter and plastid terminators using a vector comprising expression cassettes flanked by soybean plastid sequences from a region encoding the 16S rRNA, trnV and rps12.

von Allmen teaches the sequence of the portion of the soybean plastid genome that encodes the 16S rRNA, trnV and rps12.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by McBride et al, to replace the tobacco flanking regions with the corresponding ones from soybean plastid as described in von Allmen. One of ordinary skill in the art would have been motivated to do so because plastid transformation works by homologous recombination (Maliga et al, column 21 lines 30-45), and

one of skill in the art would know that the higher the homolog between the targeting segment and the target, the higher the probability of transformation. Thus, one of skill in the art would wish to use a vector comprising soybean plastid targeting sequence when transforming soybean. One of skill in the art would use targeting sequences based on the sequence taught by von Allmen because it corresponds to the region Maliga et al has shown works effectively in tobacco and because the sequence for that region is readily available. Maliga et al teaches that the targeting segment should be relatively large (column 21, lines 46-55); thus one of skill in the art would use SEQ ID NO:1 and 2, or similar sequences, made by isolating the DNAs by PCR using primers based on von Allmen's sequence. The exact breakpoint would be one of personal choice, and one of skill in the art would reasonably choose the breakpoint such that one flanking region comprises the 16SrRNA and a portion of trnV and the other comprises the rest of trnV and rps12/7

Applicant urges that persons of skill in the art would not be motivated to combine Maliga and von Allmen because at the time of filing there was no reasonable expectation that fertile transplastomic leguminous plants could be obtained, as making them had been tried and failed (response pg 14).

This is not found persuasive because Zhang et al's failure to transform soybean does not mean that soybean was considered impossible to transform; if fact, Zhang said that it should be possible (Abstract).

Applicant urges that Maliga does not enable fertile transplastomic leguminous plants for the same reasons as '391, and there would be no reason to combine Maliga and von Allmen (response pg 14).

This is not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, Applicant fails to say why one of skill in the art would not be motivated to even try the method of Maliga in view of von Allmen. Applicant fails to indicate why there was no reasonable expectation of success in producing fertile transplastomic leguminous plants. Zhang et al certainly contradicts that (abstract).

Applicant urges that prior to the present application no one had obtained fertile transplastomic leguminous plants, citing Daniell 2005 and Zhang (response pg 14).

This is not found persuasive. '391 claimed stably transformed transplastomic leguminous plants. Further, even presuming that others had failed, the history of science is full of examples of researchers succeeding where others failed. Why would anyone think that soybean plastid transformation could never be done? Applicant fails to explain why one of skill in the art would think that Maliga in view of von Allmen would not work.

Conclusion

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 10, 2008

/Anne R. Kubelik/
Primary Examiner, Art Unit 1638